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SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A.
P.O. BOX 2938
MINNEAPOLIS, MN 55402

EXAMINER	
SMITH, TERRI L	

ART UNIT	PAPER NUMBER
3762	

DATE MAILED: 10/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/675,920	KNAPP ET AL.	
	Examiner	Art Unit	
	Terri L. Smith	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 April 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-45* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-45* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *30 September 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4-27-06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

1. Applicant's arguments with respect to claims 11, 16, 21, 30, 40 and 44–45 have been considered but are moot in view of the new ground(s) of rejection necessitated by amendment.

2. Applicant's arguments filed on 27 April 2006 have been fully considered but they are not persuasive. Examiner respectfully disagrees with Applicant's argument regarding claims 1, 3, 4, 6, and 12–14. In the Office Action mailed on 27 January 2006, Examiner pointed to Figs. 2–3 as showing the claimed limitations. Specifically, for claim 1, an electrode includes a coating on at least a portion of a surface of an electrode is shown as elements 24' and 24'' where the insulating sheath is the coating on at least a portion of a surface of an electrode, a coating including two or more layers, with a first layer adjacent a surface of an electrode including an insulative material is shown as elements 24' and 24''and a second layer adjacent a first layer including at least one pharmacological agent is shown as elements 34 and 56 which includes at least one pharmacological agent as cited in column 3, lines 50–51 where porous coating 34 is wet with a drug. Examiner did not cite the sintered metal porous coating 34 to be insulative as alleged by the Applicant. Claims 3, 4, 6, and 12–14 that depend from parent claim 1, which has been shown to include every element of the claimed invention argued by the Applicant, remain rejected as originally cited in said Office Action.

3. Regarding Applicant's argument that claims 18–20 are not anticipated by the cited reference of their parent claim 16 is moot in view of the new ground(s) of rejection necessitated by amendment for the parent claim.

4. With respect to Applicant's argument that claims 33–34 are not anticipated by the cited reference of their parent claim 30 is moot in view of the new ground(s) of rejection necessitated by amendment for the parent claim.

5. Concerning claims 35, 36, 41, and 42, Examiner respectfully disagrees with Applicant's argument that the cited reference does not include each limitation recited in the claim. In the aforementioned Office Action on page 5 in subparagraph 7, Examiner pointed to Fig. 2 as showing the claimed limitations. Specifically, for claim 35, coating an electrode with a first layer is represented as 38, tine sheath in Fig. 2, wherein a first layer comprises a polymeric base coat is described in column 3, lines 31–33 as being fabricated of polyurethane or other suitable polymer; and coating an electrode with a second layer is represented by coating material 72 as described in column 5, line 62, wherein a second layer comprises a polymer is described in column 5, lines 34–41 and at least one pharmacological agent is described in column 5, lines 62–64, and at least partially coats a first layer at 58, the neck area in Fig. 2. Vachon et al. discloses the sheath 24 at least partially covered with a second layer comprising a polymer and at least one pharmacological agent at 58, the neck area in Fig. 2. Claims 36, and 41–42 that depend from parent claim 35, which has been shown to include every element of the claimed invention argued by the Applicant, remain rejected as originally cited in said Office Action.

6. Regarding claims 2, 5, 8–10, 15, 17, 31, 32, 37–39 and 43, in response to Applicant's argument that there is no suggestion to combine the references, the Examiner recognizes that references cannot be arbitrarily combined and that there must be some reason why one skilled in the art would be motivated to make the proposed combination of primary and secondary references. *In re Nomiyal*, 184 USPQ 607 (CCPA 1975). However, there is no requirement that

a motivation to make the modification be expressly articulated. The test for combining references is what the combination of disclosures taken, as a whole would suggest to one of ordinary skill in the art. *In re* McLaughlin, 170 USPQ 209 (CCPA). References are evaluated by what they suggest to one versed in the art, rather than by their specific disclosures. *In re Bozek*, 163 USPQ 545 (CCPA) 1969. In this case, Examiner has shown herein above every element of the claimed invention for parent claims 1 and 35 and has stated that Applicant's arguments with respect to claim 16 are moot in view of the new ground(s) of rejection necessitated by amendment and has addressed Applicant's arguments regarding what the prior art discusses and what it does and does not have. Additionally, Examiner did not use the MacGregor reference to cite a first layer adjacent to the electrode surface including an insulative material as alleged by the Applicant. With respect to claim 8, Examiner has cited Tsuboi et al., U.S. Patent 6,985,777 in support of the position taken in the well known in the art rejection. Applicant's argument regarding claims 31 and 32 is related to amended parent claim 30 and is moot in view of the new ground(s) of rejection necessitated by amendment to the parent claim.

7. Applicant's arguments with respect to claims 22–26, and 27–29 are moot in view of the new ground(s) of rejection necessitated by amendment for the parent claim 16. Consequently, Applicant's traversal of the single reference rejection under 35 U.S.C. § 103 is moot as well. Further, regarding Applicant's assumption that Examiner took Official Notice of the missing elements, Applicant did not specify for which missing elements and which single rejection Examiner allegedly took Official Notice Examiner. Examiner used two single reference obviousness rejections in rejecting the claims being addressed by Applicant regarding the claims in this section. To address Applicant's Official Notice assumption, Examiner quoted case law to

reject claim 21 (for which Applicant's argument is moot in view of the new ground(s) of rejection necessitated by amendment for claim 21), and Examiner has provided a reference herein above (paragraph 6) in support of the position taken in the well known in the art rejection for claim 24.

8. Applicant's arguments regarding claims 44 and 45 are moot in view of the new ground(s) of rejection necessitated by amendment to claim 44 and from which claim 45 depends.

9. Consequently, in view of the Examiner specifically pointing out where each and every element of the claimed invention is disclosed in all references, Examiner maintains the rejection as set forth in the Office Action mailed on 27 January 2006 to the extent of the claims that were not impacted by the new ground(s) of rejection necessitated by amendment.

Claim Rejections - 35 USC § 112

10. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. Claims 11and 40 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The subject matter, which was not described in the original specification, is the third layer regulates the release of the pharmacological agent from the "second layer" in combination with the other elements in the claims. Applicant's original specification discloses the originally

claimed limitation of the third layer regulates the release of the pharmacological agent from the matrix on page 6 in lines 5–7.

Claim Rejections - 35 USC § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office Action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

13. Claims 1, 3, 4, 6, 7, and 12–14 are rejected under 35 U.S.C. § 102(b) as being anticipated by Stokes, U.S. Patent 4,506,680.

14. Regarding claim 1, Stokes discloses an electrical lead comprising a lead body and an electrical conductor (Figs. 1–3); and an electrode coupled to an electrical conductor (Figs. 2–3), wherein an electrode includes a coating on at least a portion of a surface of an electrode (Figs. 2–3), a coating including two or more layers, with a first layer adjacent a surface of an electrode including an insulative material and a second layer adjacent a first layer including at least one pharmacological agent (Figs. 2–3; column 3, lines 50–51; column 1, lines 65–68).

15. Stokes discloses a pharmacological agent comprises an anti-arrhythmic agent, an angiogenic growth factor, an anti-inflammatory agent, an anti-proliferative agent, or a combination thereof (claims 3, 6, 13) (column 1, lines 65–68); an anti-inflammatory agent is dexamethasone, clobetasol, beclomethasone, or a pharmaceutically acceptable salt thereof (claims 4, 7, 14) (column 2, lines 1–2); an outer layer, wherein an outer layer includes at least one pharmacological agent (claim 12) (column 4, lines 50–54).

16. Claims 16, 18, 35; 36, 41, 42, 44 and 45 are rejected under 35 U.S.C. § 102(b) as being anticipated by Vachon et al., U.S. Patent 5,324,324.

17. With respect to claims 16 and 35, Vachon et al. disclose an electrical pulse generator (column 1, line 16); an electrical lead releasably coupled to electrical pulse generator (Fig. 1), wherein an electrical lead includes a lead body and an electrical conductor (Fig. 1); and an electrode coupled to an electrical conductor (Figs. 1–2), wherein an outer surface of an electrode is coated with two or more layers (38, tine sheath and 72, coating material) comprising a first layer including an insulative material (38, tine sheath wherein it is inherent that the sheath material is insulative to prevent creating a short with the conductive electrode with which it is in direct contact) and a second layer over a first layer (Figs 2–3, 72 over 38 at 58, the neck area), a second layer including at least one pharmacological agent (column 4, lines 30–32; column 5, lines 62–64) (claim 16); coating an electrode with a first layer (Fig. 2), wherein a first layer comprises a polymeric base coat (column 3, lines 31–33); and coating an electrode with a second layer, wherein a second layer comprises a polymer and at least one pharmacological agent, and at least partially coats a first layer (Fig. 2; column 5, lines 34–41 and 62–64) (claim 35)

18. Vachon et al. disclose a pharmacological agent comprises an anti-arrhythmic agent, an angiogenic growth factor, an anti-inflammatory agent, an anti-proliferative agent, or a combination thereof (column 4, lines 30–32) (claims 18, 36 and 42); an outer layer, wherein an outer layer comprises at least one pharmacological agent (column 5, lines 62–64) (claim 41); a coating is applied by contacting an exterior of and electrode and a composition comprising at least one polymer and at least one pharmacological agent (Figs. 2–3; column 5, lines 34–41 and 62–64) (claim 44); contacting includes spraying (column 4, lines 46–48) (claim 45).

Claim Rejections - 35 USC § 103

19. The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office Action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

20. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103(a), the Examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the Examiner to consider the applicability of 35 U.S.C. § 103(c) and potential 35 U.S.C. § 102(e), (f) or (g) prior art under 35 U.S.C. § 103(a).

21. Claims 30, 33 and 34 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Stokes in view of Sirhan et al., U.S. Patent Application 2003/0083646.

22. Regarding claim 30, Stokes discloses an electrical lead comprising a lead body and an electrical conductor (Fig. 1); and an electrode coupled to an electrical conductor (Fig. 1), wherein an electrode includes a coating on at least a portion of a surface of an electrode (34 and 56) and implant of an electrode (column 3, lines 50–52). Stokes does not disclose a coating including three or more layers, with an inner layer including a pharmacological agent in a polymer matrix for regulated, chronic release of a pharmacological agent and an outer layer including only a pharmaceutical agent such that a pharmaceutical agent of an outer layer is exposed to tissue upon implant, and a middle layer between an inner layer and an outer layer, a

middle layer including a porous polymer barrier. However, Sirhan et al. disclose a coating including three or more layers (Fig. 2I and 2K), with an inner layer including a pharmacological agent in a polymer matrix for regulated, chronic release of a pharmacological agent (40) and an outer layer including only a pharmaceutical agent such that a pharmaceutical agent of an outer layer is exposed to tissue upon implant of an electrode (55), and a middle layer between an inner layer and an outer layer, a middle layer including a porous polymer barrier (43) to provide for improved controlled substance delivery to the target tissue site. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified invention of Stokes to include a coating including three or more layers, with an inner layer including a pharmacological agent in a polymer matrix for regulated, chronic release of a pharmacological agent and an outer layer including only a pharmaceutical agent such that a pharmaceutical agent of an outer layer is exposed to tissue upon implant, and a middle layer between an inner layer and an outer layer, a middle layer including a porous polymer barrier, as taught by Sirhan et al. to provide for improved controlled substance delivery to the target tissue site.

23. With respect to claims 33 and 34, Sirhan et al. disclose a pharmaceutical agent in a polymer matrix includes an anti-inflammatory drug (claim 33) (paragraph [0042], lines 1–3) and an anti-proliferative drug (claim 34) (paragraph [0042], lines 1–2 and 5–6).

24. Claim 2 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Stokes as applied to claim 1 above, and in view of Berthelsen, U.S. Patent 4,953,564.

25. Stokes discloses the essential features of the claimed invention as described above except for an electrode includes a helical tip. However, Berthelsen discloses an electrode includes a helical tip (Figs. 1–3) to assist in delivering a drug from a controlled release device and limiting it to the immediate vicinity of the distal end of the lead, rather than allowing the drug to be dispersed into the blood stream (column 1, lines 62–66). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified invention of Stokes to include an electrode includes a helical tip, as taught by Berthelsen to assist in controlled delivery of a drug.

26. Claims 5 and 8 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Stokes as applied to claim 1 above, and in view of Vachon et al., U.S. Patent 5,324,324.

27. Regarding claim 5, Stokes discloses a first layer comprises a polymeric base coat on an electrode surface and a second layer at least partially covers a polymeric base coat (Figs. 2–3). Stokes does not disclose a second layer comprises a matrix including a polymer and at least one pharmacological agent (claim 5). However, Vachon et al. disclose a second layer comprises a matrix including a polymer and at least one pharmacological agent (Fig. 2; column 5, lines 34–41 and 62–64) to suppress or reduce the inflammatory response and growth of the fibrous capsule. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the invention of Stokes to include a second layer comprises a matrix including a polymer and at least one pharmacological agent, as taught by Vachon et al. to suppress or reduce the inflammatory response and growth of the fibrous capsule.

28. With respect to claim 8, Stokes discloses the claimed invention except for a coat is ethylene vinyl alcohol. It would have been an obvious to a person of ordinary skill in the art at

the time the invention was made to modify the polymeric base coat as taught by Stokes, to be ethylene vinyl alcohol, since it is well known in the art that hydrophilic polymers are easily absorbed by the body with no adverse effects and, advantageously, can deliver therapeutic agents effectively. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the invention of Stokes to include ethylene vinyl alcohol to effectively facilitate delivery of therapeutic agents.

29. Claims 9, 10 and 15 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Stokes as applied to claim 1 above, and in view of MacGregor, U.S. Patent 4,281,669.

30. Stokes does not disclose a third layer above a second layer, wherein a third layer includes a porous barrier (claim 9) and a porous barrier comprises a polymeric coating (claim 10) and a first layer is adapted to functionally increase an impedance of the electrode (claim 15). However, MacGregor discloses a third layer includes a porous barrier and a porous barrier comprises a polymeric coating and a first layer is adapted to functionally increase an impedance of the electrode (Fig. 2) to promote the formation of a smooth thin adherent tissue coating on the porous surface rendering the same resistant to the formation of blood clots normally associated with the presence of foreign bodies in the blood stream (column 1, lines 51–56) and to provide excellent wear and strength characteristics in the cardiovascular implant or device (column 3, lines 48–51). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the invention of Stokes to include a third layer above a second layer, wherein a third layer includes a porous barrier and a porous barrier comprises a polymeric coating, as taught by MacGregor to enhance the electrode's function when implanted.

31. Claim 11 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Stokes and MacGregor as applied to claim 9 above, and further in view of Vachon et al., U.S. Patent 5,324,324.

32. MacGregor discloses a third layer (Fig. 2), but neither MacGregor nor Stokes discloses that it regulates the release of a pharmacological agent from a second layer. However, Vachon et al. disclose that a layer regulates the release of a pharmacological agent from a second layer (ABSTRACT, line 10; column 5, lines 34–35, 41–44, 62–64, 12–14 and 29–31; column 6, lines 26–29) to ensure optimum dispensing of the pharmacological agent to the desired treatment site. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the modified inventions of Stokes and MacGregor to include a layer regulates the release of a pharmacological agent from a matrix, as taught by Vachon et al. to ensure optimal treatment of the affected site.

33. Claim 17 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Vachon et al. as applied to claim 16 above, and in view of Berthelsen, U.S. Patent 4,953,564.

34. Vachon et al. disclose the essential features of the claimed invention as described above except for an electrode includes a helical tip. However, Berthelsen discloses an electrode includes a helical tip (Figs. 1–3) to assist in delivering a drug from a controlled release device and limiting it to the immediate vicinity of the distal end of the lead, rather than allowing the drug to be dispersed into the blood stream. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified invention of Vachon

et al. to include an electrode includes a helical tip, as taught by Berthelsen to assist in controlled delivery of a drug.

35. Claims 19, 21, 22, 23, 24, 28, 29, 37 and 43 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Vachon et al. as applied to claims 16, 18, 36 and 42 above, and in view of Stokes, U.S. Patent 4,506,680.

36. Regarding claim 21, Vachon et al. disclose a second layer comprises a polymer and at least one pharmacological agent matrix on a polymeric base coat (72) (claim 21). Vachon et al. do not disclose a first layer comprises a polymeric base coat on an electrode surface. However, Stokes discloses a first layer comprises a polymeric base coat on an electrode surface (24', insulative polyurethane sheath) to facilitate ease of implantation and subsequent drug delivery. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the invention of Vachon et al. to include a first layer comprises a polymeric base coat on an electrode surface, as taught by Stokes to facilitate ease of implantation and subsequent drug delivery.

37. With respect to claims 22 and 28, Vachon et al. disclose a pharmacological agent comprises an anti-arrhythmic agent, an angiogenic growth factor, an anti-inflammatory agent, an anti-proliferative agent, or a combination thereof (column 4, lines 30–31).

38. With respect to claim 24, Vachon et al. and Stokes disclose the essential features of the claimed invention as described above except for a coat is ethylene vinyl alcohol. It would have been an obvious to a person of ordinary skill in the art at the time the invention was made to modify the polymeric base coat as taught by Stokes, to be ethylene vinyl alcohol, since one of

ordinary skill in the art would have known that hydrophilic polymers are easily absorbed by the body with no adverse effects and, advantageously, can deliver therapeutic agents effectively. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the modified invention of Stokes to include ethylene vinyl alcohol to effectively facilitate delivery of therapeutic agents.

39. Regarding claims 19, 20, 23, 29, 37 and 43, Vachon et al. do not disclose and an anti-inflammatory agent is dexamethasone, clobetasol, beclomethasone, or a pharmaceutically acceptable salt thereof (claim 19, 23, 29, 37, 43) and an anti-inflammatory agent is dexamethasone (claim 20). However, Stokes discloses an anti-inflammatory agent is dexamethasone, clobetasol, beclomethasone, or a pharmaceutically acceptable salt thereof and an anti-inflammatory agent is dexamethasone (column 2, lines 1–2) to render a chronic reduction of pacing and sensing thresholds. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the invention of Vachon et al. to include an anti-inflammatory agent is dexamethasone, clobetasol, beclomethasone, or a pharmaceutically acceptable salt thereof and an anti-inflammatory agent is dexamethasone, as taught by Stokes to render a chronic reduction of pacing and sensing thresholds.

40. Claims 25–27 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Vachon et al. and Stokes as applied to claim 21 above, and further in view of MacGregor, U.S. Patent 4,281,669.

41. Regarding claims 25 and 26, Vachon et al. disclose a layer regulates the release of a pharmacological agent from a matrix (column 5, lines 34–41, 62–64, 12–14 and 29–33; column

6, lines 26–29). Vachon et al. and Stokes do not disclose a third layer, wherein a third layer comprises a porous barrier. However, MacGregor discloses a third layer, wherein a third layer comprises a porous barrier (Fig. 2) to promote the formation of a smooth thin adherent tissue coating on the porous surface rendering the same resistant to the formation of blood clots normally associated with the presence of foreign bodies in the blood stream (column 1, lines 51–56). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the modified inventions of Vachon et al. and Stokes to include a third layer comprises a porous barrier, as taught by MacGregor to enhance the electrode's function when implanted.

42. With respect to claim 27, Vachon et al. and Stokes disclose the essential features of the claimed invention as described above except for a fourth layer. It would have been obvious to one of ordinary skill in the art at the time the invention was made to include a fourth layer, since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8.

43. Claim 31 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Stokes and Sirhan et al. as applied to claim 30 above, and further in view of Berthelsen, U.S. Patent 4,953,564.

44. Stokes and Sirhan et al. discloses the essential features of the claimed invention as described above except for an electrode includes a helix. However, Berthelsen discloses an electrode includes a helix (Figs. 1–3) to assist in delivering a drug from a controlled release device and limiting it to the immediate vicinity of the distal end of the lead, rather than allowing

the drug to be dispersed into the blood stream. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the modified inventions of Stokes and Sirhan et al. to include an electrode includes a helix, as taught by Berthelsen to assist in controlled delivery of a drug.

45. Claim 32 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Stokes and Sirhan et al. as applied to claim 30 above, and further in view of MacGregor, U.S. Patent 4,281,669.

46. Stokes discloses an electrode (Figs. 2–3). Sirhan et al. disclose a third layer directly adjacent a surface (Figs. 2I and 2K, element 16). Neither Stokes nor Sirhan et al. disclose a polymer primer layer, with an inner layer adjacent a poly primer layer. However, MacGregor discloses a polymer primer layer, with an inner layer adjacent a poly primer layer (Fig. 2) to provide excellent wear and strength characteristics in the cardiovascular implant or device. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the modified inventions of Stokes and Sirhan et al. to include a polymer primer layer, with an inner layer adjacent a poly primer layer, as taught by MacGregor to enhance the electrode's function when implanted.

47. Claims 38–40 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Vachon et al. as applied to claim 35 above, and in view of MacGregor, U.S. Patent 4,281,669.

48. With respect to claim 38, Vachon et al. disclose the claimed invention except for a coat is ethylene vinyl alcohol. It would have been an obvious to a person of ordinary skill in the art at

the time the invention was made to modify the polymeric base coat as taught by Stokes, to be ethylene vinyl alcohol, since it is well known in the art that hydrophilic polymers are easily absorbed by the body with no adverse effects and, advantageously, can deliver therapeutic agents effectively. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the invention of Vachon et al. to include ethylene vinyl alcohol to effectively facilitate delivery of therapeutic agents.

49. Regarding claims 39 and 40, Vachon et al. discloses a layer regulates the release of the pharmacological agent from a second layer (claim 40) (ABSTRACT, line 10; column 5, lines 34–35, 41–44, 62–64, 12–14 and 29–31; column 6, lines 26–29), but does not disclose a third layer, wherein a third layer comprises a porous barrier (claim 39). However, MacGregor discloses a third layer, wherein a third layer comprises a porous barrier (Fig. 2) to promote the formation of a smooth thin adherent tissue coating on the porous surface rendering the same resistant to the formation of blood clots normally associated with the presence of foreign bodies in the blood stream (column 1, lines 51–56). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the invention of Vachon et al. to include a third layer, wherein a third layer comprises a porous barrier, as taught by MacGregor to enhance the electrode's function when implanted.

Conclusion

50. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Tsuboi et al., U.S. Patent 6,985,777 discloses a hydrophilic polymer as ethylene vinyl alcohol.

51. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office Action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this Final Action is set to expire THREE MONTHS from the mailing date of this Action. In the event a first reply is filed within TWO MONTHS of the mailing date of this Final Action and the Advisory Action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the Advisory Action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the Advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this Final Action.

52. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Terri L. Smith whose telephone number is 571-272-7146. The Examiner can normally be reached on Monday - Friday, between 7:30 a.m. - 4:00 p.m..

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Angela Sykes can be reached on 571-272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

TLS
September 29, 2006
29 September 2006

GEORGE R. EVANISKO
PRIMARY EXAMINER
10/9/6